



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/563,743	07/10/2006	Christopher John Lawson	VOS0052/US	4138

33072 7590 01/30/2009
KAGAN BINDER, PLLC
SUITE 200, MAPLE ISLAND BUILDING
221 MAIN STREET NORTH
STILLWATER, MN 55082

EXAMINER

KRISHNAN, GANAPATHY

ART UNIT	PAPER NUMBER
----------	--------------

1623

MAIL DATE	DELIVERY MODE
-----------	---------------

01/30/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.		Applicant(s)	
	10/563,743		LAWSON ET AL.	
	Examiner		Art Unit	
	Ganapathy Krishnan		1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 October 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The amendment filed 10/23/2008 has been received, entered and carefully considered.

The following information provided in the amendment affects the instant application:

1. New Claims 32-36 have been added.
3. Claims 1, 8 and 11 have been amended.
3. Remarks drawn to rejections under 35 USC 112, second paragraph, 102 and 103.

Claims 1-36 are pending in the case.

The rejection of Claims 1-31 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention has been overcome in view of applicants arguments and amendments. Therefore the rejection is withdrawn.

The rejection of Claims 25, 27 and 29 under 35 U.S.C. 102(b) as being anticipated by Li et al (Carbohydrate Research, 2001, 331, 1-7) has been overcome in view of amendments. Li teaches a triose modified with the steroid diosgenin. The instant claims are drawn to the steroid part being tomatidine or demissidine, which are not taught by Li. Therefore the rejection is withdrawn.

The rejection of Claim 1-5 and 10-18 35 U.S.C. 102(e) as being anticipated by Shahid (WO 03/018604) and the rejection of Claim 30 under 35 U.S.C. 102(e) as being anticipated by Shahid (WO 03/018604) have been overcome in view of applicants' amendments to instant

Art Unit: 1623

claim 1. Shahid teaches a glucopyranoside with the steroid solasidine and not tomatidine or demissidine as instantly claimed. Therefore the rejections are withdrawn.

The following rejection is made of record necessitated by amendment.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

Art Unit: 1623

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rettegi et al (Acta Chimica Academiae Scientiarum Hungaricae Tomus, 1967, 52(1), 79-82; document cited in IDS of 1/6/2006) newly cited in view of Tamura (Trends in Glycoscience and Gycotechnology, 2001, 13(69), pages 65-88) of record and Li et al (Carbohydrate Research, 2001, 331, 1-7) of record.

Rettegi et al, drawn to steroid glycosides teach (page 79, first two lines of second paragraph and page 81, preparation of compound III) the preparation of solasidine glucoside by reacting solasidine (a steroid; compound of formula instant general formula III) with acetyl protected bromo glucose (compound of instant general formula IIa). This teaching is seen to meet the key steps as instantly claimed.

However, Rettegi does not teach the use of the steroids, tomatidine and demissidine as instantly claimed and some specific hydroxyl protections in the sugar moiety.

Tamura, drawn to synthesis of glycosaminoglycans, teach the use of ketal protected sugar 40 (page 69) for building a sugar chain wherein the addition of a sugar moiety is directed at the unprotected hydroxyl at the 3 position to give structure 42 (page 68). Even though Tamura's teaching does not deal with the synthesis of a steroid modified triose as instantly claimed one of skill in the art will recognize from his teaching that a sugar moiety such as formula 40 of Tamura could be used to make a triose via the method as instantly claimed.

Art Unit: 1623

According to Li et al, steroid modified sugars similar to the ones instantly claimed show medicinal properties like antitumor, haemostatic and immunomodulating effects (see introduction).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make a steroid modified triose of instant formula Ia or Ib starting with the sugar of formula IIa or IIb since an analogous glucosyl product of instant formula Ia is seen to be taught in the prior art.

One of skill in the art would be motivated to make the triose of instant formula since analogous products are taught to have potent antineoplastic, haemostatic and immunomodulating activity. One of skill in the art would look for other similar products that may be more potent than the glucosyl analog and would want to make the galactosyl analog too. One of skill in the art will also recognize that the same process steps could be used for the galactosyl analog containing only one rhamnose moiety by choice of the order of addition of the sugar moieties, based on the teachings of the prior art. The addition of the second and third sugar moieties to arrive at the final products Ia or Ib is well within the skill level of the artisan based on the teachings of the prior art. Applicants have also admitted in their remarks that other than the key steps, the skilled artisan can readily determine the step before and after the recited steps in order to make the end product using their knowledge of the chemical processes (Remarks, page 13, last paragraph).

Response to Applicants Remarks

Applicants have amended instant claim 1 to limit the steroid to tomatidine and demissidine. The rejection under 35 USC 103(a) as above is made of record.

Conclusion

Claims 1-36 are rejected

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ganapathy Krishnan whose telephone number is 571-272-0654. The examiner can normally be reached on 8.30am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1623

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ganapathy Krishnan/

Examiner, Art Unit 1623

/Shaojia Anna Jiang/

Supervisory Patent Examiner, Art Unit 1623